UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/963,368	11/03/1997	GARRY P. NOLAN	A-64260-2/DJ	9991

24353 7590 06/05/2003

BOZICEVIC, FIELD & FRANCIS LLP
200 MIDDLEFIELD RD
SUITE 200
MENLO PARK, CA 94025

EXAMINER
WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
1639	35

DATE MAILED: 06/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/963,368	NOLAN, GARRY P.	
	Examiner	Art Unit	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *03 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-21,23-28,30 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-21,23-28,30 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *34* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Claims

Claims 16-21, 23-28 and 30-31 are pending in the application and under examination.

Claims 22 and 29 have been canceled in the Amendment of 2/3/03.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 16-21, 23-28 and 30-31 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a practical asserted utility or a well-established utility for reasons advanced in the last Office action.

Response to Arguments

Applicants argue that the use and sale of libraries of compounds is well known in the biological and chemical arts. One of skill in the art would appreciate the commercial value of such libraries and their utility. In response, the commercial value of such libraries does not have any bearing as to the utility requirement of the statute. The court in *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966), expressed the opinion that all

chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately apparent or fully disclosed "real world" utility. Applicants further argued that the Office has recognized the utility and commercial value of libraries of agents as such libraries have been patented. Each case is treated on a case-to-case basis. Applicants argue that the presently claimed invention meets the requirement of specific and substantial utility. But fails to recite just exactly what is the specific or substantial utility of the claimed library.

Claims 16-21, 23-28 and 30-31 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a practical asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

See the rejection above.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-21, 23-38 and 30-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to provide a description of a nucleic acid wherein the candidate bioactive agent encodes a 100 amino acid residue with a randomized portion. It is not apparent from the disclosure the position, kind and/or length of amino acids in the 100-residue peptide sequence that can be randomized. More importantly, the specification does not describe whether a nucleic acid encoding a 100-residue peptide sequence has been transfected into a mammalian cell without destroying the cell's function. At the time of applicants' invention, it is well known in the art that it is not possible to predict what effect the insertion of a foreign sequence into the protein will have on the protein or the genetic package *a priori*. Likewise, it is not possible to predict which variations of amino acids or combinations of amino acids would

result in the proper expression of the protein and therefore proper contact with the target molecule. See applicants' statement at page 79, lines 25-26 which recites that "……..for secreted peptides the setup is more difficult as the responder cell must display the phenotype and …must trace the peptide back to the secreting cell…."

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-21, 23-28 and 30-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons set forth in the last Office action.

Response to Arguments

A). Applicants argue that the claim language in claims 16 and 21 "encoding" has been replaced with "encode". The amendment is unclear. The same term is being claimed, and as stated relates to a method step. Also, the term "insertion" is a method step claim. It is unclear as to the location in the retroviral sequence, insertion is made or as to the kind of candidate

peptide that can be inserted without destroying the retroviral function. It is unclear as to the basis by which a bioactive peptide is considered a "candidate" peptide as the claim is not a screening process. A composition should positively characterize only the components present therein. It is not clear whether the candidate bioactive agent is the randomized portion itself or only a portion of said candidate agent is randomized.

B). The rejection of claims 17-20 is withdrawn in view of the amendments to said claims 17-20.

C). Moot in view of the cancellation of claim 22.

D). Applicants argue that that claims 23-25 have been amended to clarify that in these claims the retroviral sequences further encode a fusion partner, which is translationally fused to the sequence encoding the candidate bioactive peptide. In response, the amendment made the claims more confusing as the added material relates to a process step. As stated in the last Office action, the claims do not further limit the base claim and broadens the base claim. The base claim does not recite encoding for a fusion partner. Applicants' argument as to the definition of fusion partner (page 6, lines 1-15) does not clarify the issue. The specification defines fusion partner as conferring upon all members of the library a common function or

ability, is as vague as the term itself. Also, as stated in the specification the **suitable** fusion partners are not limited to those recited therein. The metes and bounds of the fusion partner are therefore unclear and confusing as it covers different kinds, length and etc. of sequences, especially in the absence of positive showing in the specification.

E). Claims 30-31 are made more confusing with the amendments. It is not clear as to how a candidate bioactive peptide is considered intracellular. How can a candidate peptide be considered intracellular for a compound claim?

F). Moot in view of the cancellation of claim 29.

Double Patenting

Claims 16-21, 23-28 and 30-31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 47-50, 53 of copending Application No. 09/918,601('601 application) or claims 23-26 and 31-38 of S.N. 727,715('715 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons set forth in the last Office action.

Applicants submit that a provisional rejection of this type is properly addressed by allowance of one application, in the

absence of other outstanding rejections, at which time a determination of double patenting can be made based on the issued claims. In response, no claims have yet been found allowable in any of the copending applications. In the absence of terminal disclaimer, the **provisional** rejection of the claims is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 23-27 and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Jenkins et al in view of Nilsson et al (Current Opinion in Structural biology, 1992) for reasons of record.

As a preliminary matter, applicants' statement as to their priority entitlement to U.S. 6,153,380('380 Patent) is unclear as no statement was made in the last Office action.

Applicants admit that Jenkins reports combining retroviral expression cloning with random mutagenesis to identify two

activating point mutations in the common signal transducing subunit of the receptors for human granulocyte-macrophage colony stimulating factor (GM-CSF), IL-3 and IL-5 by virtue of their ability to confer factor independence on the FDC-P1 cell line. But argue that Jenkins disclose point mutations in a specific sequence. It is further argued that point mutation are single nucleotide changes and therefore do not teach or suggest insertions of sequences that encodes 4-100 length peptides. In response, the suggested teachings of Jenkins of a subunit of the receptors of e.g., GM-CSF would have suggested an inserted portion of a candidate bioactive agent as claimed. Furthermore, it is well known in the art, that one can create a library by combining these point mutations.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action

is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
May 15, 2003